

REMARKS

Claims 27, 32, 40, 42 and 43 are pending in the present application. Applicants gratefully acknowledge the withdrawal of the rejections as set forth in paragraphs 2-12 of the last office action.

Claim 42 was objected to in the last Office Action. Applicant respectfully asserts that the amendments to the claims in the June 7, 2010 response obviate the objections. Reconsideration is requested.

Claims 27 and 43 are rejected under 35 USC §102(b) as being anticipated by Daniell (WO 99/10513, Daniell publication). Applicant respectfully traverses. Applicant point out that claims 27 and 43 have been amended to recite a somatic embryo that is homoplasmic. The Daniell publication, while discussing homoplasmy of plants developed through organogenesis, does not teach or suggest nor enable the production of homoplasmic somatic embryos or homoplasmic plants produced therefrom. It is a well established tenet in patent law that the prior art must enable subject matter of a claim in order to anticipate or render obvious such claim, see *Minn. Mining & Mfg. Co. v. Chemque, Inc.* (3M), 303 F.3d 1294, 1301 (Fed Cir. 2002) and *In re Payne*, 606 F.2d 303, 314-15 (CCPA 1979). Applicants provide herewith a Declaration from Dr. Henry Daniell, the inventor of the Daniell publication, and which establishes that the Daniell publication does not teach or enable the subject matter of claims 27 and 43. In particular, the Daniell publication does not teach or enable chloroplast transformation and regeneration of a homoplasmic transformed plant via somatic embryogenesis.

As Dr. Daniell asserts, the Daniell publication does not discuss or teach methods designed for producing transplastomic plants via somatic embryogenesis. Indeed, the work provided in the present application, is to the Applicant's knowledge, the first demonstration of chloroplast transformation and regeneration of homoplasmic plants achieved through somatic embryogenesis. This is an important and remarkable achievement.

In order to assist the Examiner in understanding the importance of the Applicant's work, Applicant provides a background and context upon which the invention should be viewed.

To begin, each plant cell contains up to 10,000 copies of chloroplast genomes. In order to achieve successful chloroplast transformation, all 10,000 copies should have integrated foreign genes (homoplasmy) and there should not be a mixture of transformed and untransformed chloroplast genomes (heteroplasmy). Homoplasmy has been so far achieved in crops that produce shoots directly from leaves bombarded with foreign genes. When plants produce shoots directly from leaves, this process is described as organogenesis. When heteroplasmic condition is observed, these shoots are cut into small pieces and regenerated again under stringent selection conditions to eliminate untransformed chloroplasts or wild type chloroplast genomes. After several rounds of selection, homoplasmic shoots are obtained.

However, several plant species do not regenerate via organogenesis but each embryogenic cell forms an embryo. This is called a somatic (vegetative) embryo to distinguish it from embryos that are usually formed after sexual reproduction. The somatic embryo then gives rise to the shoot and root. It is not possible to chop embryos to small pieces and regenerate shoots to achieve homoplasmy. Although chloroplast transformation was achieved via organogenesis in 1990, until the invention set forth in the present application, chloroplast transformation via somatic embryogenesis has been elusive and unsuccessful in several laboratories around the world. The Applicant identified several challenges and overcame these challenges to achieve chloroplast transformation via somatic embryogenesis. These included identifying appropriate regulatory sequences and selectable marker(s) that function in non-green and green chloroplasts, and being able to regenerate chloroplast transgenic plants via somatic embryogenesis and achieve homoplasmy, which lacks the benefit of subsequent rounds of regeneration offered by organogenesis. Understanding and manipulating the somatic embryogenesis system, which lacks the advantage of subsequent rounds of regeneration from heteroplasmic tissues, added to the difficulty and complexity of the Applicant's endeavor.

The Applicant recognized that during transformation, transformed non-green plastids must develop into mature chloroplasts and transformed cells will need to survive the selection process during all stages of development. Therefore, another major challenge was to discover how to provide plastids an ability to survive selection in the light and the dark, at different developmental stages. This was absolutely critical because Applicant recognized that only one or two chloroplasts are transformed in a plant cell after bombardment and that these plastids will need to have the ability to survive the selection pressure, multiply and establish themselves while all other untransformed plastids are eliminated in the selection process. Therefore, leading to the Applicant's ultimate goal of achieving chloroplast transformation in plants that regenerate via somatic embryogenesis, the Applicant had to develop and create suitable chloroplast vectors, had to properly deliver DNA into competent recipient cells and ensure integration into one or two chloroplast genomes (heteroplasmy). Further, the Applicant had to devise a system that was capable of replacing all native (wild type) chloroplast genomes with transformed chloroplast genomes to achieve homoplasmy, inducing somatic embryos from homoplasmic embryogenic cells and regenerating transgenic plants. Through substantial effort and expertise, the Applicant was able to resolve each of these identified requirements and sets forth the fruit of his labor in the present application. Indeed, it must be noted that the present application represents, for the FIRST time, a complete and enabled process to achieve chloroplast transformation in plants that regenerate via somatic embryogenesis.

Though the work disclosed in the Daniell publication represents a remarkable achievement in its own right, the publication does not contemplate the particular hurdles outlined above, nor solutions and method of overcoming those hurdles. Thus, the Daniell publication does not provide the requisite teaching that would enable one skilled in the art to achieve chloroplast transformation through somatic embryogenesis. Therefore, it cannot be reasonably said that the Daniell publication teaches all of the elements of claims 27 and 43, as required for anticipation. In view of the foregoing remarks and

Declaration, Applicant respectfully requests reconsideration of this 35 USC 102(b) rejection.

Claims 27, 32, 40 and 42-43 are rejected under 35 USC 103(a) as being obvious over the Daniell publication in view of Adams et al. and the Daniell patent (U.S. Patent 7,129,391). Applicant respectfully traverses. The Examiner notes that the Daniell publication and the Daniell Patent include the same disclosure. Moreover, the Examiner notes that the Daniell publication does not teach the formation of a somatic embryo of transplastomic maize. In view of this noted deficiency, the Examiner cites to the Adams et al. reference. Unfortunately, the Adams et al. reference does not cure the deficiencies of the Daniell publication and Daniell patent. Though Adams et al. discusses somatic embryogenesis in maize, it does not contemplate much less address the unique hurdles that had to be overcome to achieve a chloroplast transformation and regeneration through somatic embryogenesis. As discussed above for the 102(b) rejection, a combination of the cited art fails to enable regeneration of a stable transplastomic and homoplasmic plant via somatic embryogenesis. Without such enablement and teaching, the cited art cannot be considered to render the rejected claims obvious. In addition, dependent claims 42 and 43 set forth additional features that further distinguish them over the cited art. In view of the foregoing amendments, remarks and Daniell Declaration, Applicants respectfully request reconsideration of this rejection.

In view of the foregoing remarks and amendments, Applicants respectfully assert that all claims are in a condition for allowance and request that a notice of allowance be issued.

Respectfully submitted,

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